K001886

JUL 12 2000

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
Apex® Fixation Pins

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|---|---|
| **Proprietary Name:** | Apex® Fixation Pins |
| **Common Name:** | Fixation Pin |
| **Classification Name and Reference:** | Smooth or threaded metallic bone fixation fastener.<br>21 CFR §888.3040 |
| **Proposed Regulatory Class:** | Class II |
| **Device Product Code:** | OR (87) JDW |
| **For Information contact:** | Jennifer A. Daudelin, Regulatory Affairs<br>Howmedica Osteonics Corp.<br>359 Veterans Boulevard<br>Rutherford, NJ 07070-2584<br>(201) 507-7283<br>Fax: (201) 507-6870 |

This Special 510(k) submission is intended to address a sterilization modification to the Apex® Fixation Pins. The intended use, design, materials, and manufacturing methods remain identical to those of the predicate device. The predicate Apex® Fixation Pins are fixation pins available in a range of diameters, overall lengths, and thread lengths. The tips are beveled in three dimensions to create a smoother, more efficient cutting edge. The tip is also slightly wider than the shank to reduce friction between the shank and bone. Tiny spoon shaped ~~grooves located~~ along the tip enable it to cut away hard cortical bone for cleaner, more precise entry and exit holes. The predicate device was found substantially equivalent via the 510(k) process. The current version of the Apex® pins are sold non-sterile, and the individual Apex® pins will continue to be sold non-sterile. The modification is to provide the pins as part of a sterile kit terminally sterilized by exposure to a minimum of 25 kiloGrays of gamma radiation from a Cobalt-60 source to provide a minimum sterility assurance level of $10^{-6}$.

The intended use of the modified device, as described in its labeling, has not changed as a result of this modification. These devices are intended to be inserted into the bone nearest a fracture site and connected externally to a rigid external supporting frame for immobilization of unstable fractures. The pins are designed to ease bone penetration and minimize the risk of friction thermal necrosis, thereby facilitating secure bone purchase and stable fixation of the fracture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2000

Ms. Jennifer A. Daudelin
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K001886
Trade Name: Apex® Fixation Pins
Regulatory Class: II
Product Code: JDW
Dated: June 20, 2000
Received: June 21, 2000

Dear Ms. Daudelin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bechtner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: Apex® Fixation Pins

Indications for Use:

The Apex® Fixation Pins are intended to be used in conjunction with a rigid external supporting frame for immobilization of open and/or unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

(Division Sign-Off)
Division of General Restorative Devices

Prescription Use ✓ OR Over-The-Counter Use 510(k) Number K001886
(Per 21 CFR 801.109)

(Optional Format 1-2-96)